Visceral leishmaniasis (VL) is a disease caused by intracellular protozoan parasite that spread by a female sand fly vector. If left untreated, this disease is fatal and is characterized by prolonged fever, splenomegaly, hepatomegaly, pancytopenia. India is one of the most important foci in the world for VL. The number of cases of VL per year in India is approximately 22,100. Of these cases, the state of Bihar accounts for more than 90%. Asymptomatic, infected persons are presumed to be carriers and may play a significant role in transmission of the disease. Seroepidemiologic data from disease-endemic areas of India are scarce and based on small sample sizes. Serologic analysis of infection was conducted using the direct agglutination test (DAT) and rK39 antigen strip test because of their ease of use in community-based studies and reliable sensitivity and specificity. To quantify incidence of infection, 200 households in the hyperendemic community of the Sahebganj block of Muzaffarpur district were selected for this study. Persons who never had VL and had no fever in past month were enrolled into the study. Children less than three years of age were excluded; 870 healthy persons living in the disease-endemic area were included. Enrolled persons were divided into two groups: those from families in which there were members who currently or previously had VL (household group) and those from families with no history of VL (neighbor group). Longitudinal follow-up was conducted up to two years at intervals of three months, six months, one year, and two years. The DAT and a commercially available rK39 antigen strip test (Kalazar Detect; InBios, Seattle, WA) were used for serologic analysis. Of the 870 persons, 574 were from the household group and 296 were from the neighbor group. Serologic analysis showed that 120 (13.79%) persons were positive by the rK39 antigen strip test and 230 (26.43%) were positive by the DAT. Only 63 persons (7.24%) were positive by both assays. Overall, 287 (33%) persons were seropositive by either test. There was no significant difference in rK39 antigen strip test results between the household (14.11%) and neighbor (13.17%) groups. However, using data from the DAT, we observed that the household group had a significantly higher frequency of positive persons (28.4%) than the neighbor group (22.82%; \( P = 0.04 \); Table 1). Of the persons followed-up for 2 years, 25 (2.87%) developed clinical VL. There was no significant difference in disease conversion among seropositive persons (15 of 583, 2.57%) and seronegative persons (10 of 283, 3.48%). Of 63 (7.24%) persons who were positive by both tests, only one showed disease conversion. Among 25 persons who showed disease conversion, 15 (3.84%) were males and 10 (2%) were females. Among the seropositive group, at the end of three months, six months, one year, and two years, three, one, two, and four persons, respectively, showed disease conversion. Among the seronegative group, one, five, five, and four persons, respectively, showed disease conversion. Of 25 persons who showed disease conversion, 13 (3%) were 3–15 years of age and 12 (2.73%) were > 15 years of age. However, the difference between these groups was not significant. Interestingly, of the 25 persons who showed disease conversion, 24 were from households with VL cases (4.18%), whereas only 1 was from the neighbor group (0.33%; \( P = 0.0013 \)). This finding indicated that persons from households with VL cases are at a significantly greater risk of developing overt disease regardless of their serologic status than their neighbors. The difference in disease conversion between persons from households with VL cases and their neighbors has also been observed in a study in Bangladesh. A high prevalence of seropositive but asymptomatic persons in areas endemic for VL has been reported. In our study, 287 (33%) persons were serologically positive. Only 10 (3.48%) seropositive persons showed disease conversion. However, 15 (2.57%) seronegative persons at baseline showed disease conversion. Our findings differ from those of previous studies in India in which disease conversion was extremely high in the seropositive group. The present study had a much larger sample size with follow-up of entire cohort irrespective of serologic results. Prior studies did not consider the serologically negative group. However, the variation in findings is difficult to explain if persons included are not properly screened for early disease or they developed the disease a short time after testing. High conversion rates would be erroneously reported. Significantly higher disease conversion rates in households with VL patients indicate increased susceptibility compared with that in households without any incidence of VL irrespective of rate of seropositivity.
Genetic susceptibility to Leishmania spp. infection has been reported in human VL.15,16 Thus, on the basis of our study, we recommend that serologic status is not a good predictor for conversion to clinical VL. Because serologic analysis using the DAT and rK39 antigen strip test were performed only at the baseline and further follow-up was conducted without serologic analysis, our study may have failed to detect seroconversion of persons who developed clinical VL during follow-up.

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